Department of LABOR AND INDUSTRIES

Published by
Health Services Analysis Section
Olympia, WA 98504-4322

# PROVIDER BULLETIN

PB 03-02

## THIS ISSUE

**Coverage Decisions**

**TO:**

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Hospitals
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## Purpose

This Provider Bulletin describes the following decisions:



The Provider Bulletin becomes effective on 2/19/2003 for State Fund and Self-Insurance claims in all locations.

## Autologous Chondrocyte Implantation

### What is Autologous Chondrocyte Implantation?

Autologous chondrocyte implantation (ACI) may treat patients with cartilaginous defects of the femoral condyle. The ACI process involves:

- obtaining healthy chondrocyte cells from a patient's knee.
- culturing the cells through a process termed Carticel.
- implanting the cultured chondrocytes back into the patient via a surgical procedure.

### When is ACI a covered procedure?

Carticel and ACI are covered procedures in patients who meet ALL of the following criteria.

A. An acute, work-related trauma to the knee caused the cartilaginous lesion. For example, the full-thickness cartilage loss is secondary to a shearing injury or a direct blow.

**AND**

B. Evidence shows a single, clinically significant, symptomatic lesion.

i. The lesion affects a load-bearing surface of the medial femoral condyle or the lateral femoral condyle.

and

ii. The full-thickness lesion (Modified Outerbridge Grade III-IV[1]) involves only cartilage.

and

iii. The lesion measures between 1 to 10 $cm^2$ in area.

**AND**

C. Evidence shows that the knee is stable and has:
   i. Intact, fully functional menisci and ligaments,
      and
   ii. Normal alignment,
      and
   iii. Normal joint space.

**AND**

D. The patient attempted and failed BOTH of the following treatments for the lesion:
   i. Appropriate non-surgical treatment (e.g., minimum 2 months of physical therapy),
      and
   ii. Traditional surgical intervention (i.e., microfracture, drilling, abrasion, osteochondral graft). Debridement alone does not constitute a traditional surgical intervention for these purposes.

**AND**

E. The patient has the following characteristics:
   i. Less than 60 years old,
      and
   ii. Body Mass Index < 35, [2]
      and
   iii. Is capable and willing to follow the rehabilitation protocol.

## When is ACI not a covered procedure?

ACI is not a covered procedure in any of the following circumstances.

A. The lesion that requires treatment:
   i. Involves any portion of the patellofemoral articular cartilage,
      or
   ii. Involves bone,
      or
   iii. Is due to osteochondritis dissecans.

**OR**

B. A "kissing lesion" of Modified Outerbridge Grade II, III, or IV exists on the opposing tibial surface.

**OR**

[1]

| **Modified Outerbridge Classification** | |
|---|---|
| I | Articular cartilage softening |
| II | Chondral fissures or fibrillation < 1.25 cm in diameter |
| III | Chondral fibrillation > 1.25 cm in diameter, ("crabmeat changes") |
| IV | Exposed subchondral bone |

The Outerbridge classification first appeared in 1961 and referred only to radiographic changes. (Outerbridge, RE. *J Bone Joint Surg*. 1961; 43:752-757) Many authors have reported improved outcome predictability when radiographic findings are combined with observations made at the time of arthroscopy. The "Modified Outerbridge Classification" represents many similar grading scales that are referred to as "Outerbridge" in current medical literature.

[2] According to the Centers for Disease Control, the equation to calculate Body Mass Index = (Weight in pounds ÷ Height in inches ÷ Height in inches) x 703. For example, a person weighing 210 pounds and 6 feet tall would have a BMI = 210 pounds divided by 72 inches divided by 72 inches multiplied by 703 = 28.5. Using the metric formula, BMI = (Weight in kilograms ÷ Height in cm ÷ Height in cm) x 10,000. For example, a person weighing 95.3 kilograms and 182.9 centimeters tall would have a BMI = 95.3 kg divided by 182.9 cm divided by 182.9 cm x 10,000 = 28.5

C. The patient has an arthritic condition that appears on standing X-rays as joint space narrowing, osteophytes, or changes in the underlying bone. The insurer will exclude a patient if the inflammatory (rheumatoid or other) or degenerative (osteoarthritis) arthritis is any of the following.

i. Mild and diffuse
or
ii. Moderate to severe and localized
or
iii. Moderate to severe and diffuse

**OR**

D. The patient has an unhealthy cartilage border. The synovial membrane in the joint may be used as a substitute border for up to ¼ of the total circumference.

**OR**

E. The patient has undergone a total meniscectomy of either compartment in the affected knee. The compartment in which the patient will receive ACI must contain at least 1/3 of the posterior meniscal rim.

**OR**

F. The patient has a history of anaphylaxis to Gentamicin or a sensitivity to materials of bovine origin.

**OR**

G. Chondrocalcinosis is diagnosed during the cell culturing process.

### Whom will the Insurer reimburse for ACI?

The Insurer will reimburse physicians who have completed Genzyme Tissue Repair's training course on ACI. In addition, physicians must:

A. Have performed or assisted on 5 or more ACI procedures.

**OR**

B. Perform ACI under the direct supervision and control of a surgeon who has performed 5 or more ACI procedures.

Only physicians who meet these requirements should bill for ACI. Payment authorization for ACI is premised upon the Insurer's understanding that only surgeons meeting the stated criteria will perform the procedure.

### What documentation does the physician submit?

Documentation needs to address all of the requirements for a covered procedure. The Insurer may require physicians to submit the following documents to define the patient's knee condition.

A. Operative notes
B. Reports of standing X-rays
C. Arthroscopy results

### Does payment for ACI require prior authorization?

Yes, the Insurer requires prior authorization for payment of each stage of ACI. Physicians first request payment for an initial arthroscopy and then request payment for ACI.

To initiate the reviews for a State Fund claim, physicians submit their requests to the Department's utilization review (UR) contractor, Qualis Health. UR makes a recommendation to the Claim Manager to authorize or to deny the request for payment. The Claim Manager makes the final determination. The procedure for requesting payment and performing ACI for a State Fund candidate follows:

| | |
|---|---|
| Physician | 1. submits a request for an arthroscopy to UR |
| UR | 2. reviews case<br>3. sends recommendation to Claim Manager |
| Claim Manager | 4. authorizes arthroscopy<br>5. notifies physician of decision |
| Physician | 6. performs an arthroscopy and harvests cells<br>7. sends cells to Genzyme<br>8. asks Genzyme to hold cells<br>9. assesses patient's candidacy based on criteria<br>10. submits request for ACI to UR<br>11. awaits authorization from the Insurer |
| UR | 12a. reviews case<br>12b. sends recommendation to Claim Manager |
| Genzyme | 12c. holds cells<br>12d. awaits notification from physician |
| Claim Manager | 13. authorizes payment for the cell culture<br>14. authorizes payment for the implantation procedure<br>15. notifies physician of decision |
| Physician | 16. authorizes Genzyme to culture cells after receiving payment approval<br>17. schedules implantation procedure |
| Genzyme | 18. cultures cells<br>19. sends cultured cells to operating room<br>20. bills the Insurer for culturing the cells |
| Physician | 21. receives cells<br>22. performs implantation procedure |

### What are the billing codes for ACI?

| Procedure | CPT Code | Abbreviated Description |
|---|---|---|
| Initial Arthroscopy and Cell Harvest | 29870 | Knee arthroscopy, with or without synovial biopsy |
| | 29877 | Knee arthroscopy with debridement of articular cartilage |
| Implantation | 27599 | Unlisted procedure, femur or knee |

| Procedure | HCPCS Code | Abbreviated Description |
|---|---|---|
| Cell Culture | J7330 | Autologous cultured chondrocytes |

On the request form for ACI, physicians include the codes for cell culture and implantation. However, physicians only submit a bill for the implantation procedure. Genzyme Biosurgery submits a bill for Code J7330 directly to the Insurer.

## Meniscal Allograft Transplantation

### What is meniscal allograft transplantation?

Meniscal allograft transplantation involves surgically grafting a donor meniscus into the knee of a patient. Patients who have undergone meniscal repair procedures and meniscectomy may benefit from the procedure because the replacement meniscus may reestablish load bearing, shock absorption, and joint stability. Reducing stress on the tibial plateau may also help to prevent osteoarthrosis development. The options for graft preservation include freshly transplanting, fresh-freezing, cryopreserving, or lyophilizing the tissue.

### When is meniscal allograft transplantation a covered procedure?

Meniscal allograft transplantation in one or more compartments is a covered procedure if the patient and the affected compartment meet ALL of the following inclusion criteria.

A. An acute, work-related trauma to the knee previously caused the need for a meniscectomy that removed at least two-thirds of the meniscus.

**AND**

B. The patient's knee pain has not responded to conservative treatment.

**AND**

C. The articular cartilage in the affected compartment demonstrates a chondrosis classified by the Modified Outerbridge Scale as:
   - i. Grade I,
     or
   - ii. Grade II,
     or
   - iii. Grade III. If Grade III, then debridement must first produce an articular surface sufficiently free of irregularities in order to maintain the integrity of the transplanted meniscus.

**AND**

D. Evidence shows that the knee is stable and has:
   - i. Sufficient articular cartilage in the affected compartment to ensure the continued integrity of the allograft meniscus,
     and
   - ii. Intact ligaments,
     and
   - iii. Normal alignment,
     and
   - iv. Normal joint space.

**AND**

E. The patient meets the following characteristics.
   - i. Too young or active for arthroplasty. The ideal patient age ranges from 20 to 45 years.
     and
   - ii. Body Mass Index < 35.[2]
     and
   - iii. Capable and willing to follow the rehabilitation protocol.

### When is meniscal allograft transplantation not a covered procedure?

Meniscal allograft transplantation is not a covered procedure in any of the following circumstances:

A. The patient has an arthritic condition that appears on standing X-rays as joint space narrowing, osteophytes, or changes in the underlying bone. The insurer will exclude a patient if the inflammatory (rheumatoid or other) or degenerative (osteoarthritis) arthritis is any of the following.
   i. Mild and diffuse
      or
   ii. Moderate to severe and localized
      or
   iii. Moderate to severe and diffuse

**OR**

B. The articular cartilage in the affected compartment demonstrates a chondrosis classified by the Modified Outerbridge Scale as:
   i. Grade III and has not undergone debridement.
      or
   ii. Grade III and has undergone debridement that has not produced an articular surface sufficiently free of irregularities in order to maintain the integrity of the transplanted meniscus.
      or
   iii. Grade IV.

### Whom will the Insurer reimburse for meniscal allograft transplantation?

The Insurer will reimburse physicians performing meniscal allograft transplantation when they have prior experience performing this procedure. Physicians must:

A. Have performed or assisted on 5 or more meniscal allograft transplant procedures.

**OR**

B. Perform the meniscal allograft transplant under the direct supervision and control of a surgeon who has performed 5 or more meniscal allograft transplant procedures.

Only physicians who meet these requirements should bill for meniscal allograft transplantation. Payment authorization is premised upon the Insurer's understanding that only surgeons meeting the stated criteria will perform the procedure.

### What documentation does the physician submit?

Documentation needs to address all of the requirements for a covered procedure. The Insurer may require physicians to submit the following documents to define the patient's knee condition.

A. Operative notes
B. Reports of standing, anterior-posterior, and loadbearing X-rays
C. Reports of technetium bone scan
D. Arthroscopy results
E. Reports of computerized tomography (CT) scans
F. Magnetic resonance (MR) evaluation results

### Does payment for meniscal allograft transplantation require prior authorization?

Yes, the Insurer requires prior authorization for payment of meniscal allograft transplantation.

To initiate the review for a State Fund claim, physicians submit their requests to the Department's utilization review (UR) contractor, Qualis Health. UR makes a recommendation to the Claim Manager to authorize or to deny the request for payment. The Claim Manager makes the final determination.

**What are the billing codes for meniscal allograft transplantation?**

| CPT Code | Abbreviated Description |
|---|---|
| 0014T | Meniscal Transplantation, medial or lateral, knee |

## Microprocessor-Controlled Prosthetic Knees

### What are microprocessor-controlled prosthetic knees?

Microprocessor-controlled prosthetic knees for above-the-knee amputees use computers to enhance basic mechanical knee designs. Sensors incorporated into the prosthesis gather data to determine stance phase and swing phase control. As a result, the prosthesis facilitates amputee response to changing conditions while ambulating.

### Are microprocessor-controlled prosthetic knees covered devices?

The Insurer will NOT purchase microprocessor-controlled prosthetic knees, such as the Otto Bock C-Leg, Endolite Intelligent Prosthesis Plus, or Endolite Adaptive Prosthesis.

The small number of studies on computerized knee prostheses does not conclusively show the devices' effectiveness for:

- reducing energy expenditure.
- improving ability to walk on uneven ground.
- improving ability to climb and descend stairs.
- increasing walking distance.

### Are there exceptions to the non-coverage policy?

The Insurer may authorize purchase of a microprocessor-controlled knee prosthesis for the following exception.

A. The patient's documented need for the computerized prosthesis relates to maintaining or enhancing work-related functions.
   i. The patient may require greater ability to ambulate long distances (over 400 yards) at variable rates on a daily basis at work. Use of the limb at home or for basic community ambulation does not justify provision of the computerized limb over standard applications.

**OR**

   ii. The patient may require greater ability to ambulate on uneven ground or on stairs at work. Use of the limb for limited stair climbing in the home or basic community does not justify provision of the computerized limb over standard applications.

**AND**

B. The patient has previously mastered the use of an advanced stance and swing control hydraulic unit (such as the Mauch, CaTech, or 3R80) as demonstrated by the ability to ambulate at a faster than baseline rate.

**AND**

C. The patient is a unilateral, transfemoral amputee weighing up to 220 pounds and has a moderate or higher functional level. In addition, the patient has an adequate cardiovascular reserve to allow for faster than normal walking speed.

### What are the billing codes for microprocessor-controlled prosthetic knees?

| HCPCS Code | Abbreviated Description |
|---|---|
| L5846 | Addition, endoskeletal knee-shin system, microprocessor control feature, swing phase only |
| L5847 | Addition, endoskeletal knee-shin system, microprocessor control feature, stance phase |

## The UniSpacer

### What is the UniSpacer?

The UniSpacer is a small, kidney shaped insert made of cobalt chrome for patients with early stage osteoarthritis of the knee. The UniSpacer is said to treat isolated, moderate degeneration of the medial compartment (Grade III-IV chondromalacia) with no more than minimal degeneration (Grade I-II chondromalacia, no loss of joint space) in the lateral condyle or patellofemoral compartment. The goals of UniSpacer surgery are to relieve pain and to improve joint stability by restoring ligament tension and normal knee alignment.

### Is the UniSpacer a covered device?

The UniSpacer is not a covered device at this time because of an absence of clinical data and published literature regarding its safety and efficacy. The Food and Drug Administration (FDA) has allowed the manufacturer to market the device because of the device's similarity to other hemitibial prostheses. Due to this classification as a prosthetic, the manufacturer is not required to obtain FDA approval before commercially distributing the product. As a result, the FDA has NOT approved the UniSpacer through a process documenting device safety and efficacy.

The Insurer will reconsider its decision if presented with peer-reviewed medical literature demonstrating product safety and effectiveness or if the FDA finds the device safe and effective for its intended use.

### Where is more information available?

For more information about LNI's utilization review contractor, Qualis Health, see Provider Bulletin 02-04. The Bulletin may be downloaded from http://www.lni.wa.gov/hsa/ProvBulletins/pb-pdf/PB_02-04.pdf.

For additional information about fees and billing instructions, see the Medical Aid Rules and Fee Schedules. The information may be found online at www.lni.wa.gov/hsa.

Contact Grace Wang at wann235@lni.wa.gov or (360) 902-5227 for more information about the technology assessments for ACI, meniscal allograft transplantation, or computerized prosthetic knees. The assessments are available online at www.lni.wa.gov/omd/FullTechAssessment.htm.